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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,344	08/10/2001	Michael John Davies	PC10943AJTJ	5590

7590

06/18/2003

Gregg C. Benson
Pfizer Inc.
Patent Department, MS 4159
Eastern Point Road
Groton, CT 06340

EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,344

Applicant(s)

DAVIES ET AL.

Examiner

Vickie Kim

Art Unit

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-13 is/are pending in the application.
- 4a) Of the above claim(s) 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4. 6) ☐ Other: .

DETAILED ACTION

Election acknowledged

Applicants affirmation on the election with traverse of Group I claims 1 and 3-8 is acknowledged. Applicant requested s traverse the restriction requirement on the grounds that there would be no burden in searching the entire application. This argument is not persuasive, as not all groups encompassed by the application would be classified together.

As mentioned in previous office action, each invention is found to be patentably distinct subject matter proven in numerous patent literatures. For instance, PDE5 inhibitor is used for materially different treatments(e.g. angina, hypertension, heart failure, glaucoma, asthma, erectile dysfunction, etc) other than wound treatment. The combination of PDE 5 inhibitor and uPA or MMP is known in the field and used in the treatment of materially different conditions, the restriction is proper, see WO9932150 or US5019393. Additionally, MMP inhibitor or uPA inhibitor is well used in the wound treatment as evidenced by numerous patented documents, see US5602156. Since the claimed subject matter is group I is not patenable, the restriction is deemed proper.

Furthermore, even if there were unity of classification, the search of the entire application in patent and non-patent literature (a significant part of the thorough examination) would be burdensome due to the reasons mentioned in previous office action(e.g. patentably distinct subject matter proven in numerous patent literature). The restriction requirement is deemed proper and necessary for accurate examination. Thus, the restriction is maintained, and made FINAL.

Status of Application

The claims 1 and 3-13 are pending and the elected claims 1 and 3-8 are presented for the examination. The non-elected claims 9 –13 are withdrawn from the consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-5 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. IC50 value and selectivity ratio of PDE-5 inhibitors are variable depending on the types of enzyme which the inhibitor compound is acting on. For sildenafil, for instance, IC50 for inhibition of PDE1-4 were 80-8500 times greater than that for PDE5. Thus, the claims are properly included in this rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al (abstract only, 1988) or Fritz(abstract only, 1988).

Yamamoto teaches that dipyridamole(PDE-5 inhibitor) is effectively used in the treatment of livedo vasculitis(i.e. leg ulcers), see entire abstract.

It is well known in the art that dipyridamole is PDE-5 inhibitor. Also it is noted that chronic venous ulcer is known as venous leg ulcers as evidenced by applicant's own admission(see instant specification 1, lines 17-19). Thus , the critical elements required by the instant claims are taught by the cited reference.

Fritz also teaches that dipyridamole(300mg/day) is effectively used in the treatment of ulcerated plaques or patient having carotid artery stenosis, see abstract. As evidenced by applicant's own admission(see, instant specification 1, lines 22-25), chronic arterial ulcers are caused by plaques in the arteries. Therefore, it would have

been envisaged that the effective treatment using dipyridamole(300mg/day) for ulcerative plaques results in the improvement of chronic arterial ulcers. Thus, the claimed subject matter is taught by the cited reference and properly included in this rejection.

2. Claims 1, 3-8 are rejected under 35 U.S.C. 102(e) as anticipated by Parks et al(US 6,391,869).

Parks et al teach a composition and method for treating anorectal disorders such as anal ulcers or anal fissures, wherein the composition comprising therapeutically effective amount of a phosphodiesterase V inhibitor such as sildenafil, Zaprinst or dipyridamole, see abstract, column 12, lines 57-65 and examples 5-7, 9 &12.

Especially, the patentee contemplates his invention in the example 9 (see, column 29, lines 10-38), wherein 50-600mg of sildenafil ointment is effectively treat anal ulcers, anal fissure and hemorrhoidal diseases. Furthermore, oral sildenafil tablet is also taught therein. Since anal ulcers, fissures and hemorrhoid is involving acute wounds (e.g. cuts and grazing, see instant specification at page 1, lines 33-34), it would have been envisaged to any skilled artisan that treating such conditions would promote and potentiate healing in acute wound.

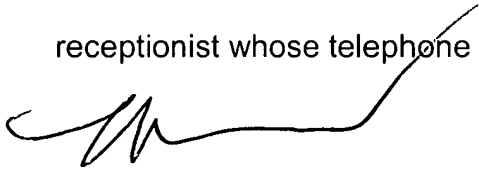
As to claims 4-5 regarding IC₅₀ value at less than 100 nanomolar or selectivity ratio are inherently possessed physical feature wherein sildenafil or Zaprinst is naturally possesses the claimed feature as evidenced by numerous scientific documents(see, PTO-892). Thus, all the claimed subject matter is not patentably distinguished over the prior art of the record.

Conclusion

3. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675.

The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Patent examiner
June 13, 2003
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